

## Attachment 7: 510(k) Summary of Safety and Effectiveness

### 1 General Information

DEC 03 2007

Submitter's Name and Address: Transoma Medical, Inc.  
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Contact Person: Lisa Stone  
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Email: [lstone@transomamedical.com](mailto:lstone@transomamedical.com)

Date of Summary: November 7, 2007

Proprietary Name of Device: Model 3000-08 Antenna Accessory Kit

Common/Usual Name: Implantable ECG Monitoring System

Classification Name: Cardiac Implantable Event Recorder  
Product Code – MXC  
21 CFR Part 870.2800  
Device Class II

Legally Marketed Device to Which Substantial Equivalence is Claimed: Sleuth Implantable ECG System  
K063035

### 2 Device Description

The Sleuth Implantable ECG System is an electrocardiogram (ECG) monitoring system that includes an implantable component and that provides continuous ECG monitoring and episodic or segmented ECG recording. The Sleuth Implantable ECG System comprises three interrelated components: Implantable Monitoring Device (IMD), Activator and Base Station.

The modification described in this Special 510(k) is the addition of an 8 cm Antenna Accessory Kit option (Model 3000-08) for use with the IMD, Model 2010.

The 8 cm antenna gives the physician an additional option. The Accessory Kit contains an 8 cm antenna and torque wrench. No changes have been made to the torque wrench.

The only difference between the original 6 cm antenna and the 8 cm antenna is the length. The antenna measures 8 cm from the IS-1 connector to tip.

### **3 Intended Use**

The Transoma Medical Sleuth Implantable ECG Monitoring System is an implantable, patient- and automatically-activated monitoring system that records subcutaneous ECG and is indicated for:

- Patients with clinical syndromes or situations at increased risk of cardiac arrhythmias
- Patients who experience transient symptoms that may suggest a cardiac arrhythmia

### **4 Summary of Technological Characteristics**

The 8 cm Antenna Accessory Kit incorporates substantially equivalent technology, comparable features, labeling, and intended use, and is similar to the predicate device currently available on the market.

### **5 Non-clinical Test Summary**

The substantial equivalence of the 8 cm Antenna Accessory Kit has been demonstrated via bench testing, including:

- Visual/dimensional inspection
- IS-1 testing
- Resistance testing
- Impedance testing
- Tensile/flexural strength testing
- Protection of the device from external defibrillation and high-power electrical fields testing
- Radiated immunity testing
- ESD immunity testing
- Electrical environmental effects (E3) testing

### **6 Conclusion**

Based on the information provided above, the 8 cm Antenna Accessory Kit is substantially equivalent to the 6 cm Antenna Accessory Kit.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

DEC 03 2007

Transoma Medical, Inc.  
c/o Ms. Lisa J. Stone, RAC  
Principal Regulatory Affairs Specialist  
4211 Lexington Ave. North, Suite 2244  
St. Paul, MN 55126-6164

Re: K073147  
Trade/Device Name: Sleuth Implantable ECG System 8 cm Antenna Accessory Kit  
Regulation Number: 21 CFR 870.2800  
Regulation Name: Implantable Cardiac Event Recorder (without Arrhythmia Detection)  
Regulatory Class: Class II (two)  
Product Code: MXC  
Dated: November 7, 2007  
Received: November 8, 2007

Dear Ms. Stone:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Bram D. Zuckerman, M.D.  
Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Attachment 4: Indications for Use Statement

510(k) Number K073147

**Device Name:** Transoma Medical Sleuth Implantable ECG Monitoring System

### Indications for Use:

The Transoma Medical Sleuth Implantable ECG Monitoring System is an implantable, patient- and automatically-activated monitoring system that records subcutaneous ECG and is indicated for:

- Patients with clinical syndromes or situations at increased risk of cardiac arrhythmias
- Patients who experience transient symptoms that may suggest a cardiac arrhythmia

Prescription Use X  
(21 CFR 801 Subpart D)

OR

Over the Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
Division Sign-Off)  
Division of Cardiovascular Devices  
510(k) Number K073147